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Honey Bee - Toxicity of Residues on Foliage

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HAZARD EVALUATION DIVISION

STANDARD EVALUATION PROCEDURE

HONEY BEE - TOXICITY OF RESIDUES ON FOLIAGE

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16. Abstract (Limit: 200 words)

The Standard Evaluation Procedure (SEP) for the Honey Bee Toxicity of Residues on Foliage is a guidance document primarily intended for Agency reviewers and the regulated industry who evaluate ecological effects data specified in 40 CFR Part 158.145. The SEP is also intended to provide information to the general public indicating how the Agency evaluates these types of studies. As such, it is designed to supplement Subdivision E of the Pesticide Assessment Guidelines: Hazard Evaluation - Wildlife and Aquatic Organisms. This SEP provides an Introduction, Materials and Methods, Reporting Requirements, Reviewer Evaluation, and Appendix of appropriate methods to guide the review and scientific evaluation of pesticide effects on honey bees.

The SEP for Honey Bee Toxicity of Residues on Foliage is only one of a number of SEP's published by the National Technical Information Service as a supplement to Subdivision E of the Pesticide Assessment Guidelines.

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STANDARD EVALUATION PROCEDURE

PREAMBLE

This Standard Evaluation Procedure (SEP) is one of a set of guidance documents which explain the procedures used to evaluate environmental and human health effects data submitted to the Office of Pesticide Programs. The SEPs are designed to ensure comprehensive and consistent treatment of major scientific topics in these reviews and to provide interpretive policy guidance where appropriate. The Standard Evaluation Procedures will be used in conjunction with the appropriate Pesticide Assessment Guidelines and other Agency Guidelines. While the documents were developed to explain specifically the principles of scientific evaluation within the Office of Pesticide Programs, they may also be used by other offices in the Agency in the evaluation of studies and scientific data. The Standard Evaluation Procedures will also serve as valuable internal reference documents and will inform the public and regulated community of important considerations in the evaluation of test data for determining chemical hazards. I believe the SEPs will improve both the quality of science within EPA and, in conjunction with the Pesticide Assessment Guidelines, will lead to more effective use of both public and private resources.

John W. Melone, Director
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HONEY BEE - TOXICITY OF RESIDUES ON FOLIAGE

I. INTRODUCTION

A. When Required

This study is required to support the registration of any pesticide intended for outdoor application, when the proposed use pattern indicates that honey bees may be exposed to the pesticide, and when the formulation contains one or more active ingredients having an acute contact honey bee LD_{50} which falls in the moderately toxic or highly toxic range (based on testing conducted under Sec. 141-1)

B. Purpose

- To establish residual toxicity levels of the formulated product to honey bees;
- To compare toxicity information with expected residues from standard rates, to assess potential hazard to honey bees;
- To provide support for precautionary label statements; and
- To indicate the need for further testing or field studies.

C. Test material

The test product shall be a typical end-use product.

II. MATERIALS AND METHODS: TESTING STANDARDS/RECOMMENDATIONS

A. Acceptable Protocols

Information useful in developing a test protocol may be obtained from the following references:

Johansen, C., C. Kious, G. Schultz, R. Gupta, R. Madsen, and W. Robinson. 1977. Bee research investigations, 1977. Dept. of Entomol., Wash. St. Univ. Unpubl. 22 pp.

Lagier, R.F., C.A. Johansen, M.G. Kleinschmidt, L.I. Butler, L.M. McDonough, and S.D. Jackson. 1974. Adjuvants decrease insecticide hazard to honey bees. Coll. of Agric. Research Center, Wash. St. Univ., Bull. 801. 7 pp.

B. Test Organisms

1. Acceptable Species

Testing shall be performed on the honey bee, Apis mellifera L.

2. Size/Age/Physical Condition

Test insects should be worker bees of uniform age. Only bees from disease-free colonies should be used, and they should be kept in conditions conforming to proper cultural practices.

C. Test Conditions

1. Test Levels

The test substance should be applied at the proposed label rates.

2. Number Per Level

The number of insects tested per concentration and the number of concentrations or dosage levels evaluated should be sufficient to yield statistically sound data. Insects should be randomly assigned to test groups to minimize bias and assure comparability of pertinent variables.

3. Controls

Tests should include concurrent control groups to determine if any observed effects have developed or occurred independent of the test substance.

III. REPORTING REQUIREMENTS

A. Test Material

The composition of the test material must be stated; percent a.i. must be reported.

B. Observations

Reporting on observations should include the following:

- Frequency, duration, and method of observation; and
- Detailed description of the nature, incidence, time of occurrence, severity, and duration of all observed toxic effects, including death and any other abnormal or unusual signs.

C. Data Analysis

Data analysis should provide the following:

- Tabulation of the response data at each treatment level;
- Methods of calculation;
- No observed effect level; and
- Statistical methods used for analysis of data.

IV. REVIEWER EVALUATION/STUDY INTERPRETATION

A. Acceptability

The reviewer should identify each aspect of the reported procedure that is inconsistent with recommended protocol. The significance of these deviations must be determined. The number of deviations and their severity will determine the validity of the study and the interpretation of the results.

B. Evaluation of Results

The reviewer should indicate what the results were and how much information can be drawn from them. The data from this study will indicate the level of a pesticide's residual toxicity to honey bees and the degree to which that toxicity decreases over time. The reviewer should use this information, along with whatever other information is available (e.g., proposed use, application instructions, use rates), to determine the hazard to honey bees. In most cases, data from this test will be used to develop bee precaution statements for the product label. If the pesticide demonstrates an unusually long period of residual toxicity, further testing may be required.

C. Conclusions

1. Categorization of Results

The significance of inconsistencies in the test procedures must be determined by the reviewer so that the results of the test can be categorized as to their usefulness in a risk assessment. Categories are described as:

- Core: All essential information was reported and the study was performed according to recommended guideline protocols. Minor inconsistencies with standard methodologies may be apparent, but the deviations do not detract from the study's soundness or intent. Studies within this category fulfill the basic requirements of Part 158 of the regulations and are acceptable for use in a risk assessment.

- Supplemental: Studies in this category are scientifically sound; however, they were performed under conditions that deviated substantially from recommended guideline protocols. Results do not meet regulatory requirements; however, the information may be useful in a risk assessment.

- Invalid: These studies provide no useful information. They may be scientifically unsound, or they were performed under conditions that deviated so substantially from recommended protocols that the results will not be useful in a risk assessment.

2. Rationale

To support a supplemental or invalid category, the reviewer must list and explain all test conditions that deviate from standard protocols.

3. Repairability

If any or all of the deviations can be reexamined and found acceptable (i.e., the study category can be upgraded), the reviewer also discusses this. Usually to upgrade a study, additional information must be requested.

D. Implications of Dose/Mortality Response

The dose/mortality response enables derivation of such useful information as the LC_{50} and 95% confidence limits as well as the NOEL. It may also reveal important characteristics about the toxicity of the test material such as whether the response is gradual over a wide concentration range of test levels or rapid with a narrow range between the NOEL and 100% mortality.

Pertinent data on dose/mortality response should be included in data evaluation records.

E. Observation of Toxic Symptoms and Behavioral Responses

Observation of toxic symptoms and behavioral responses, other than death, may be useful for evaluating the hazard of the test material.

F. Comments on Statistics

The statistics presented in the report should be verified particularly if the raw data do not show clear linear dose/mortality response or if the reported LC_{50} and confidence limits do not seem to match the raw data. Any deviation should be noted and explained if possible.